COFC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.	: 6,992,172
U.S. SERIAL NO.	: 09/710,239
INVENTOR(S)	: Chang, et al.
ISSUE DATE	: 31 January 2006
DOCKET NO.	: FP0400 US
TITLE	: RECOMBINANT GELATINS

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. 1.322

Sir:

Applicants request correction of the above-referenced issued U.S. Patent by Certificate of Correction pursuant to 37 C.F.R. 1.322. Applicants assert that mistakes in the issued patent incurred through the fault of the Office, and such mistakes are clearly disclosed by the records of the Office. Documentation supporting this assertion accompanies this request.

The text of the correction is submitted herewith on Certificate of Correction Form PTO/SB/44.

Enclosures:

1. Form PTO/SB/44 (5pgs)
2. Copy of Amendment dated 9 December 2004, received by the Office on 13 December 2004 (21pgs)
3. Copy of Proposed Examiner's Amendment dated 16 March 2005 (2pgs)
4. Copy of Notice of Allowance and Notice of Allowability mailed 30 March 2005 (8pgs)
5. Copy of Amendment under 37 C.F.R 1.312 dated 19 May 2005, received by the Office on 23 May 2005 (10pgs)
6. Copy of Response to Rule 312 Communication mailed 1 November 2005 (2pgs)

Applicants believe no fee is associated with this communication. However, should the Commissioner determine that a fee is required, authorization is hereby given to charge the total of any such fee to Deposit Account No. 50-0811. This form is enclosed in duplicate.

Certificate of mailing or transmission under 37 CFR § 1.8

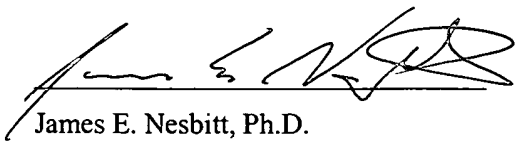
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 14 September 2006.

Name: Michael Moores Signature: _____

Please call Applicants' representative at 650.866.7289 with any questions regarding this communication or the above-referenced patent.

Respectfully submitted,

Date: 14 Sept 2006

By: 

James E. Nesbitt, Ph.D.
Reg. No. 54,575

FibroGen, Inc.
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TITLE	: RECOMBINANT GELATINS

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Alexandria VA 22313-1450

TRANSMITTAL

The following items accompany this Transmittal:

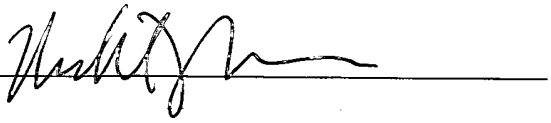
1. Return Receipt Postcard
2. Request for Certificate of Correction under 37 CFR 1.322 (2pgs)
3. Form PTO/SB/44 (5pgs)(for Request under 37 CFR 1.322)
4. Copy of Amendment dated 9 December 2004, received by the Office on 13 December 2004 (21pgs)
5. Copy of Proposed Examiner's Amendment dated 16 March 2005 (2pgs)
6. Copy of Notice of Allowance and Notice of Allowability mailed 30 March 2005 (8pgs)
7. Copy of Amendment under 37 C.F.R 1.312 dated 19 May 2005, received by the Office on 23 May 2005 (10pgs)
8. Copy of Response to Rule 312 Communication mailed 1 November 2005 (2pgs)
9. Request for Certificate of Correction under 37 CFR 1.323 (1pg)
10. Form PTO/SB/44 (1pg) (for Request under 37 CFR 1.323)

Applicants claim small entity status under 37 C.F.R. 1.27.

The Commissioner is hereby authorized to charge the total of any necessary fees to Deposit Account No. 50-0811, referencing Docket No. FP0400 US. This form is enclosed in duplicate.

Certificate of mailing or transmission under 37 CFR § 1.8

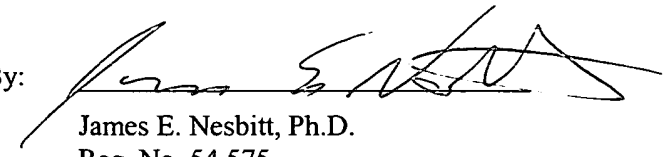
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 14 September 2006.

Name: Michael Moores Signature: 

Please call Applicants' representative at 650.866.7289 with any questions regarding this communication or the above-referenced patent.

Respectfully submitted,

Date: 14 Sept 2006

By: 

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PTO/SB/44 (04-05)
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,992,172

APPLICATION NO.: 09/710,239

ISSUE DATE : 31 January 2006

INVENTOR(S) : Chang, Robert C., et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 97, line 10, replace the text beginning with "What is claimed is:" to and ending with "of a uniform molecular weight." in column 100, line 7, with the following:

-- What is claimed is:

1. A recombinant human gelatin of a molecular weight selected from the group consisting of about 1 kDa, about 5 kDa, about 8 kDa, about 9 kDa, about 10 kDa, about 14 kDa, about 16 kDa, about 18 kDa, about 20 kDa, about 22 kDa, about 23 kDa, about 29 kDa, about 33 kDa, about 36 kDa, about 41 kDa, about 44 kDa, about 50 kDa, and about 65 kDa.

2. A recombinant human gelatin of a molecular weight range selected from the group consisting of about 1 to 50 kDa, about 50 to 100 kDa, about 100 to 150 kDa, about 150 to 200 kDa, about 200 to 250 kDa, about 250 to 300 kDa, and about 300 to 350 kDa.

3. A recombinant gelatin composition consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight, wherein the uniform molecular weight is greater than 300 kDa.

4. A recombinant human gelatin of a Bloom strength selected from the group consisting of 50, 100, 150, 200, 250, and 300.

5. A recombinant human gelatin of a Bloom strength of between 0 and 100.

6. A recombinant gelatin having a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%.

7. A recombinant gelatin composition consisting essentially of recombinant human gelatin polypeptides of a uniform molecular weight.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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225 Gateway Boulevard
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,992,172
APPLICATION NO.: 09/710,239
ISSUE DATE : 31 January 2006
INVENTOR(S) : Chang, Robert C., et al.

continued from previous page:

8. A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:18.

9. A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:29.

10. An encapsulant comprising a recombinant human gelatin.

11. A stabilizing agent comprising a recombinant human gelatin.

12. A film-forming agent comprising a recombinant human gelatin.

13. An emulsifier comprising a recombinant human gelatin.

14. A thickening agent comprising a recombinant human gelatin.

15. A colloidal agent comprising a recombinant human gelatin.

16. A hard gel capsule comprising a recombinant human gelatin.

17. A soft gel capsule comprising a recombinant human gelatin.

18. A plasma expander comprising a recombinant human gelatin.

19. A colloidal volume replacement material comprising a recombinant human gelatin.

20. A medical sponge comprising a recombinant human gelatin.

21. A pharmaceutical stabilizer comprising a recombinant human gelatin.

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APPLICATION NO.: 09/710,239

ISSUE DATE : 31 January 2006

INVENTOR(S) : Chang, Robert C., et al.

continued from previous page:

22. The pharmaceutical stabilizer of claim 21, wherein the pharmaceutical stabilizer is a vaccine stabilizer.

23. A microcarrier comprising a recombinant human gelatin.

24. An edible composition comprising a recombinant human gelatin.

25. A protein supplement comprising a recombinant human gelatin.

26. A fat substitute comprising a recombinant human gelatin.

27. A nutritional supplement comprising a recombinant human gelatin.

28. An edible coating comprising a recombinant human gelatin.

29. A photographic composition comprising a recombinant human gelatin.

30. A cosmetic composition comprising a recombinant human gelatin.

31. An industrial composition comprising a recombinant human gelatin.

32. A cell culture composition comprising a recombinant human gelatin.

33. A recombinant human gelatin of a molecular weight range selected from the group consisting of about 10 to 30 kDa, about 30 to 50 kDa, and about 50 to 70 kDa.

34. A recombinant human gelatin of a molecular weight range selected from the group consisting of about 10 to 70 kDa, about 150 to 250 kDa, and about 250 to 350 kDa.

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UNITED STATES PATENT AND TRADEMARK OFFICE
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APPLICATION NO.: 09/710,239

ISSUE DATE : 31 January 2006

INVENTOR(S) : Chang, Robert C., et al.

continued from previous page:

35. A recombinant gelatin having a percentage hydroxylation selected from the group consisting of 20 to 40%, 40 to 60%, and 60 to 80%.

36. A recombinant gelatin having a percentage hydroxylation selected from the group consisting of 20 to 30%, 30 to 40%, and 40 to 80%.

37. A recombinant gelatin having a percentage hydroxylation of 30 to 80%.

38. A recombinant gelatin having a percentage hydroxylation of 20 to 60%.

39. A recombinant gelatin having a percentage hydroxylation of 30 to 60%.

40. A recombinant gelatin having a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%, and further wherein the hydroxylation is proline hydroxylation.

41. A recombinant human gelatin produced directly by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen.

42. A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists of recombinant human gelatin polypeptides of a uniform molecular weight.

43. A pharmaceutical composition comprising a non-hydroxylated recombinant human gelatin and a pharmaceutically acceptable excipient.

44. A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%.

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PTO/SB/44 (04-05)
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APPLICATION NO.: 09/710,239
ISSUE DATE : 31 January 2006
INVENTOR(S) : Chang, Robert C., et al.

continued from previous page:

45. The pharmaceutical composition of claim 44, wherein the hydroxylation is proline hydroxylation.

46. A pharmaceutical composition comprising a recombinant human gelatin and a pharmaceutically acceptable excipient, wherein the recombinant human gelatin is produced directly by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen.

47. A recombinant gelatin consisting of recombinant human gelatin polypeptides of a uniform molecular weight. --

MAILING ADDRESS OF SENDER (Please do not use customer number below):

James E. Nesbitt, Ph.D.
FibroGen, Inc.
225 Gateway Boulevard
South San Francisco CA 94080

MEMORY TRANSMISSION REPORT

PAGE : 001
TIME : DEC-09-04 16:25
TEL NUMBER1: 6508667292
NAME : FIBROGEN. INC.

FILE NUMBER : 860

DATE : DEC-09 16:21

TO : ☎915712730948

DOCUMENT PAGES : 017

START TIME : DEC-09 16:21

END TIME : DEC-09 16:25

SENT PAGES : 017

STATUS : OK

FILE NUMBER : 860 *** SUCCESSFUL TX NOTICE ***

FIBROGEN, INC.
225 Gateway Boulevard
South San Francisco CA 94080
Main: 650-866-7200

Leanne C. Price
Vice President, Intellectual Property
Telephone (Direct): 650-866-7254
Facsimile: 650-866-7292
lprice@fibrogen.com

COVER SHEET

The attached transmission contains information of a confidential and proprietary nature subject to attorney-client privilege and is intended only for review by the addressee named below.

Date: 9 December 2004

To: Examiner Kam
Group 1653
Fax No. 571-273-0948

From: Leanne C. Price

Re: U.S. Patent Application Serial No. 09/710,239

No. of pages, including cover sheet: 17

Dear Examiner Kam:

Attached please find a courtesy copy of the Amendment and associated papers filed today, 9 December 04, in the above-referenced application.

Do not hesitate to contact me directly with any questions.

Please call Carolyn Caires at 650-866-7323 if there are any problems with transmission of this document.

FIBROGEN, INC.
225 Gateway Boulevard
South San Francisco CA 94080
Main: 650-866-7200

Leanne C. Price
Vice President, Intellectual Property
Telephone (Direct): 650-866-7254
Facsimile: 650-866-7292
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Re: U.S. Patent Application Serial No. 09/710,239

No. of pages, including cover sheet: 17

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PTO/SB/21 (01-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

U.S. Serial No.	09/710,239
Filing Date	10 November 2000
Applicant(s)	Chang et al.
Art Unit	1653
Examiner Name	C. Kam
Docket No.	FP0400 US

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Associate Power of Attorney
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

Copy of Terminal Disclaimer filed in U.S. Application Serial No. 10/232,175.

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Leanne C. Price, Esq. Reg. No. 42,090
Signature	
Date	9 December 04

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an enveloped addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on 9 December 2004.

Typed or printed	Carolyn C. Caires		
Signature	Carolyn C. Caires	Date	9 December 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-14 on 9 December 2004.

By: Carolyn C Caires

Printed: Carolyn C. Caires

PTO/SB/17 (01-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 510.00

Complete if Known	
U.S. Serial No.	09/710,239
Filing Date	10 November 2000
Applicant(s)	Chang et al.
Examiner Name	C. Kam
Art Unit	1653
Docket No.	FP0400 US

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 50-0811

Deposit Account Name: FibroGen, Inc.

The Commissioner is authorized to: *(check all that apply)*

☒ Charge any fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Highest previously Paid for		Fee from below	Fee Paid
Total Claims	47	-20** =	65	X		0.00
Independent Claims	45	- 3** =	56	X		0.00
Multiple Dependent						

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	510.00
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 510.00

SEP 22 2005

SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Leanne C. Price, Esq.	*Registration No. (Attorney/Agent)*	42,090	*Telephone*	650-866-7200
Signature				*Date*	9 Dec 04

SEP 21 2005

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

SEP 21 2005

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on 9 Dec er 2004.

By: Carolyn C. Caires

Printed: Carolyn C. Caires

PTO/SB/22 (10-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket No. FP0400 US

Applicant(s)	Chang et al.
U.S. Serial No. 09/710,239	Filing Date 10 November 2000
Title	Recombinant Gelatins
Group Art Unit 1653	Examiner C. Kam

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

- ☐ One month (37 CFR 1.17(a)(1)) $_____
- ☐ Two months (37 CFR 1.17(a)(2)) $_____
- ☒ Three months (37 CFR 1.17(a)(3)) $ 1,020.00
- ☐ Four months (37 CFR 1.17(a)(4)) $_____
- ☐ Five months (37 CFR 1.17(a)(5)) $_____

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ 510.00.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0811. I have enclosed a duplicate copy of this sheet.

I am the

☐ applicant/inventor

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a). Registration number if acting under 37 CFR 1.34(a)_____.

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9 Dec 04
Date

Signature

Leanne C. Price, Esq. Reg. No. 42,090
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

Burden Hour Statement: This form is estimated to take 0.1 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SEP 22 2005

SEP 21 2005

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 9 December 2004.

Carolyn C. Caires

Printed: Carolyn C. Caires

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Chang et al.	Assignee:	FibroGen, Inc.
Serial No.:	09/710,239	Filing Date:	10 November 2000
Examiner:	C. Kam	Group Art Unit:	1653
Title:	RECOMBINANT GELATINS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

The courtesies of Examiner Kam and Examiner Weber in the interview of 7 December 2004 are much appreciated. In response to the Office Action dated 09 June 2004 (Office Action), the period for response having been extended until 09 December 2004 by the accompanying petition and fee, please consider the above-identified application in view of the following amendments and remarks.

IN THE CLAIMS

Please amend claims 2, 3, 4, 5, 6, 8, 12, 76, 77, 78, 79, 80, 81, 82, 83, 89, 90, 92, 93, and 98.

A complete list of all claims in the application, including previously canceled claims and previously amended claims, follows.

1. (Previously Canceled)

2. (Currently Amended) A recombinant human gelatin of ~~having~~ a molecular weight selected from the group consisting of about 1 kDa, about 5 kDa, about 8 kDa, about 9 kDa, about 10 kDa, about 14 kDa, about 16 kDa, about 18 kDa, about 20 kDa, about 22 kDa, about 23 kDa, about 29 kDa, about 33 kDa, about 36 kDa, about 41 kDa, about 44 kDa, about 50 kDa, and about 65 kDa.

3. (Currently Amended) A recombinant human gelatin of ~~having~~ a molecular weight range selected from the group consisting of about ~~0~~ 1 to 50 kDa, about 50 to 100 kDa, about 100 to 150 kDa, about 150 to 200 kDa, about 200 to 250 kDa, about 250 to 300 kDa, and about 300 to 350 kDa.

4. (Currently Amended) A recombinant gelatin composition consisting essentially of recombinant gelatin polypeptides ~~having~~ of a uniform molecular weight, wherein the uniform molecular weight is greater than 300 kDa.

5. (Currently Amended) A recombinant human gelatin of ~~having~~ a Bloom strength selected from the group consisting of 50, 100, 150, 200, 250, and 300.

6. (Currently Amended) A recombinant human gelatin of ~~having~~ a Bloom strength of between 0 and 100.

7. (Previously Canceled)

8. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%.

9. (Previously Canceled)

10. (Previously Canceled)

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11. (Previously Canceled)

12. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin composition consisting essentially of~~, wherein the recombinant gelatin comprises homogeneous~~ recombinant gelatin polypeptides of a uniform molecular weight.

13. (Previously Canceled)

14. (Previously Canceled)

15. (Previously Canceled).

16. (Previously Canceled)

17. (Previously Canceled)

18. (Previously Canceled)

19. (Previously Canceled)

20. (Previously Canceled)

21. (Previously Amended) A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:18.

22. (Previously Canceled)

23. (Previously Canceled)

24. (Previously Canceled)

25. (Previously Canceled)

26. (Previously Canceled)

27. (Previously Canceled)

28. (Previously Canceled)

29. (Previously Canceled)

30. (Previously Amended) A recombinant gelatin comprising the amino acid sequence of SEQ ID NO:29.

31. (Previously Canceled)

32. (Previously Canceled)

33. (Previously Canceled)

34. (Previously Canceled)

35. (Previously Canceled)

36. (Previously Canceled)

37. (Previously Canceled)

38. (Previously Canceled)

39. (Previously Canceled)

40. (Previously Canceled)

41. (Previously Canceled)

42. (Previously Canceled)

43. (Previously Amended) An encapsulant comprising a recombinant human gelatin.

44. (Previously Amended) A stabilizing agent comprising a recombinant human gelatin.

45. (Previously Amended) A film-forming agent comprising a recombinant human gelatin.

46. (Previously Canceled)

47. (Previously Amended) An emulsifier comprising a recombinant human gelatin.

48. (Previously Amended) A thickening agent comprising a recombinant human gelatin.

49. (Previously Canceled)

50. (Previously Amended) A colloidal agent comprising a recombinant human gelatin.

51. (Previously Canceled)

52. (Previously Canceled)

53. (Previously Canceled)

54. (Previously Amended) A hard gel capsule comprising a recombinant human gelatin.

55. (Previously Amended) A soft gel capsule comprising a recombinant human gelatin.

56. (Previously Amended) A plasma expander comprising a recombinant human gelatin.

57. (Previously Amended) A colloidal volume replacement material comprising a recombinant human gelatin.

58. (Previously Canceled)

59. (Previously Amended) A medical sponge comprising a recombinant human gelatin.

60. (Previously Canceled)

61. (Previously Amended) A pharmaceutical stabilizer comprising a recombinant human gelatin.

62. (Previously Amended) A microcarrier comprising a recombinant human gelatin.

63. (Previously Canceled)

64. (Previously Amended) An edible composition comprising a recombinant human gelatin.

65. (Previously Amended) A protein supplement comprising a recombinant human gelatin.

66. (Previously Amended) A fat substitute comprising a recombinant human gelatin.

67. (Previously Amended) A nutritional supplement comprising a recombinant human gelatin.

68. (Previously Amended) An edible coating comprising a recombinant human gelatin.

69. (Previously Canceled)

70. (Previously Amended) A photographic composition comprising a recombinant human gelatin.

71. (Previously Amended) A cosmetic composition comprising a recombinant human gelatin.

72. (Previously Amended) An industrial composition comprising a recombinant human gelatin.

73. (Previously Amended) A cell culture composition comprising a recombinant human gelatin.

74. (Previously Canceled)

75. (Previously Added) The pharmaceutical stabilizer of claim 61, wherein the pharmaceutical stabilizer is a vaccine stabilizer.

76. (Currently Amended) A recombinant human gelatin of ~~having~~ a molecular weight range selected from the group consisting of about 10 to 30 kDa, about 30 to 50 kDa, and about 50 to 70 kDa.

77. (Currently Amended) A recombinant human gelatin of ~~having~~ a molecular weight range selected from the group consisting of about 10 to 70 kDa, about 150 to 250 kDa, and about 250 to 350 kDa.

78. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation selected from the group consisting of 20 to 40%, 40 to 60%, and 60 to 80%.

79. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation selected from the group consisting of 20 to 30%, 30 to 40%, and 40 to 80%.

80. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation of 30 to 80%.

81. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation of 20 to 60%.

82. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation of 30 to 60%.

83. (Currently Amended) A ~~composition comprising a~~ recombinant gelatin~~, wherein the recombinant gelatin has~~ having a percentage hydroxylation selected from the group

consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%, and further wherein the hydroxylation is proline hydroxylation.

84. (Previously Canceled)

85. (Previously Canceled)

86. (Previously Canceled)

87. (Previously Canceled)

88. (Previously Canceled)

89. (Currently Amended) A ~~composition comprising a~~ recombinant human gelatin~~, wherein the recombinant human gelatin is~~ produced directly ~~from an altered collagen construct~~ by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen.

90. (Currently Amended) A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists of ~~comprises homogeneous~~ recombinant gelatin polypeptides of a uniform molecular weight.

91. (Previously Canceled)

92. (Currently Amended) A pharmaceutical composition comprising a non-hydroxylated recombinant human gelatin and a pharmaceutically acceptable excipient.~~, wherein the recombinant human gelatin is non-hydroxylated.~~

93. (Currently Amended) A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0 to 20%, 20 to 80%, and 80 to 100%.

94. (Previously Added) The pharmaceutical composition of claim 93, wherein the hydroxylation is proline hydroxylation.

95. (Previously Canceled)

96. (Previously Canceled)

97. (Previously Canceled)

98. (Currently Amended) A pharmaceutical composition comprising a recombinant human gelatin and a pharmaceutically acceptable excipient, wherein the recombinant human gelatin is produced directly ~~from an altered collagen construct~~ by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen.

Please add new claim 99:

99. (Added herein) A recombinant gelatin consisting of recombinant gelatin polypeptides of a uniform molecular weight.

REMARKS

Justification for the amendments is as follows. Support for the amendment to claim 3 is found, for example, at page 32, line 10, of the specification as filed. Support for amended claims 4, 12, and 90 is found throughout the specification, for example, at page 31, line 27. Claims 89 and 98 as amended are supported, e.g., at page 23, lines 20-23, of the specification. The recombinant gelatin of new claim 99 finds support throughout the specification, at least at, for example, page 31, line 27. Examiner Kam and Examiner Weber's indication that these claims would be allowable as amended herein is much appreciated. The remaining amendments to the claims were made to further clarify the present invention. No new matter is added by any of the above amendments.

I. Claim Status

Claims 1-74 were originally filed, and were subject to restriction. In response to the Restriction Requirement dated 09 July 2001, Applicants elected with traverse the claims of Group I, claims 1-21, 30, and 42-74. In the Amendment dated 16 August 2002, claims 1, 22-29, 31-41, 52, and 63 were canceled without prejudice to their renewal and claim 75 was added. In the Amendment dated 24 June 2003, claims 16-20, 46, 53, and 74 were canceled without prejudice to their renewal and claims 76-98 were added. In the Amendment dated 15 March 2004, claims 9, 13, 14, 15, 42, 49, 51, 58, 60, 84, 85, 86, 87, 88, 91, 95, 96, and 97 were canceled without prejudice to their renewal.

Claims 2, 3, 4, 5, 6, 8, 12, 76, 77, 78, 79, 80, 81, 82, 83, 89, 90, 92, 93, and 98 are amended herein, and new claim 99 is added. Therefore, claims 2-6, 8, 12, 21, 30, 43-45, 47, 48, 50, 54-57, 59, 61, 62, 64-68, 70-73, 75-83, 89, 90, 92-94, 98, and 99 are pending. In the Office Action dated 09 June 2004, the Examiner indicated that claims 5, 6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, and 92-94 are allowable.

II. Rejection of claims 2, 3, 8, 12, 21, 61, 75, and 98 under the doctrine of obviousness-type double patenting

The Examiner provisionally rejected claims 2, 3, 8, 12, 21, 61, 75, and 98 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12-18, and 47-48 of copending U.S. Patent Application Serial No. 10/232,175. Applicants note that a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) was filed in association with commonly owned and copending U.S. Patent Application No. 10/232,175, a copy of which terminal disclaimer is attached to this Amendment for the Examiner's convenience. As a terminal disclaimer was filed in association with copending U.S. Patent Application Serial No. 10/232,175, the provisional rejection of claims 2, 3, 8, 12, 21, 61, 75, and 98 under the judicially created doctrine of obviousness-type double patenting is thus moot. Withdrawal of the rejection of these claims under the judicially created doctrine of obviousness-type double patenting is therefore respectfully requested.

III. Rejection of claims 3, 89, and 98 under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 3, 89, and 98 under 35 U.S.C. § 112, second paragraph. With respect to claim 3, the Examiner stated that the term "about 0 to 50 kDa" rendered the claim indefinite. (See Office Action, page 5, subsection 12.) The term "about 0 to 50 kDa" does not appear in amended claim 3 above. With respect to claims 89 and 98, the Examiner stated that the term "altered collagen construct" rendered these claims indefinite. (Office Action, page 5, subsection 13.) Applicants submit that the term "altered collagen construct" as recited in claims 89 and 98 would be understood by a person of skill in the art in view of the specification, at least for the reasons earlier described. However, in order to expedite prosecution of the present application, the term "altered collagen construct" does not appear in the claims as amended. Specifically, claims 89 and 98 are amended above to recite that the claimed recombinant gelatins are "produced directly by expression of a polynucleotide sequence that contains at least one collagenous domain and that does not encode naturally occurring collagen." The Examiners' indication in the interview of 7 December 2004 that the above amendments to claims 3, 89, and 98 would overcome the rejection of these claims under 35 U.S.C. § 112, second paragraph, is appreciated. In view of the above discussion, withdrawal of the rejection of these claims under 35 U.S.C. § 112, second paragraph, is respectfully requested.

IV. Rejection of claims 4, 12, and 90 under 35 U.S.C. § 102(e)

The Examiner rejected claims 4, 12, and 90 under 35 U.S.C. § 102(e) as being anticipated by Wunderlich et al. (U.S. Patent No. 6,068,854).

Wunderlich describes microencapsulation of a pharmaceutical substance using a mixture of different gelatin types, and states that a "particularly homogeneous distribution of the microencapsules" can be obtained using a mixture of different gelatin types "with identical or similar molecular weight distribution." (See Wunderlich, column 8, lines 33-36.) Claim 4 as amended above is directed to a recombinant gelatin composition "consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight, wherein the uniform molecular weight is greater than 300 kDa." Wunderlich does not disclose recombinant gelatins "of a uniform molecular weight," and therefore fails to anticipate claim 4.

Amended claim 12 recites "[a] recombinant gelatin composition consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight." As noted above, Wunderlich fails to disclose recombinant gelatins "of a uniform molecular weight." For at least this reason, Wunderlich does not anticipate amended claim 12.

Finally, claim 90 is amended above to recite "[a] pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists recombinant gelatin polypeptides of a uniform molecular weight." As described, *supra*, Wunderlich does not disclose recombinant gelatins "of a uniform molecular weight," and, therefore, does not anticipate claim 90 as amended above.

As Wunderlich does not anticipate amended claims 4, 12, and 90, withdrawal of the rejection of these claims as being anticipated under 35 U.S.C. § 102(e) by Wunderlich is respectfully requested.

CONCLUSION

The Examiner's withdrawal of the previous rejections and objections and the Examiner's indication that claims 5, 6, 30, 43-45, 47, 48, 50, 54-57, 59, 62, 64-68, 70-73, 76-83, and 92-94 are allowable are much appreciated. Further, the indication of the Examiner and Supervisory Examiner Weber in the interview of 7 December 2004 that the claims as amended herein would be allowable is greatly appreciated. In view of the above amendments and arguments, Applicants believe that the present application is now in condition for allowance.

Please call Applicant's Attorney directly at 650-866-7254 with any questions regarding this communication.

Respectfully submitted,

Date: 9 December 2004

By:

Leanne C. Price
Reg. No. 42,090

FIBROGEN, INC.
225 Gateway Boulevard
South San Francisco CA 94080
Main: 650-866-7200
Direct: 650-866-7254
Facsimile: 650-866-7292

SEP 22 2005

I hereby certify that this correspondence is being transmitted by facsimile to Patent Technology Center 1600, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450, at 703-872-9306 on 30 December 2004.

By: Carolyn C. Caires

Printed: Carolyn C. Caires

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Chang et al.		
Title:	RECOMBINANT GELATINS IN VACCINES		
Serial No.:	10/232,175	Filing Date:	30 August 2002
Examiner:	Y. Kim	Group Art Unit:	1644

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TERMINAL DISCLAIMER

Sir:

FIBROGEN, INC., with its place of business at 225 Gateway Boulevard, South San Francisco CA 94080, is the Assignee of 100 percent interest in and is the owner of U.S Patent Application Serial No. 10/232,175, filed 30 August 2002, entitled " RECOMBINANT GELATINS IN VACCINES," as evidenced by the Assignment recorded in the United States Patent and Trademark Office on 13 March 2001, at Reel 011646, Frame 0232, in prior application U.S. Serial No. 09/710,249, from which the present application claims priority under 35 U.S.C. 120. Pursuant to 37 C.F.R. § 1.321(c), FIBROGEN, INC., the owner, disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on co-pending U.S. Patent Application Serial No. 09/710,239, filed on 10 November 2000, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said co-pending application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the co-pending application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the co-pending application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors, or its assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said co-pending application, as the term of any patent granted on said co-pending application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the co-pending application, in the event that any such patent granted on the co-pending application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Applicants believe that no fee is due with this communication. If, however, the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge any necessary fees to Deposit Account No. **50-0811**. **This form is enclosed in duplicate.** If there are any questions regarding this communication, please call the undersigned at 650-866-7200.

Respectfully submitted,

DATE: 03 Dec. 2004

James E. Nesbitt, Ph.D.
Reg. No. 54,575

FIBROGEN, INC.
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South San Francisco CA 94080
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Facsimile: 650-866-7292

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chang et al. Date Mailed: 9 December 2004

Serial No.: 09/710,239 Filed: 10 November 2000

Title: RECOMBINANT GELATINS

Assignee: FibroGen, Inc.

Docket No.: FP0400 US

Please confirm receipt of the following items by return receipt of this postcard:

1. Transmittal (1 page).
2. Fee Transmittal (1 page, in duplicate).
3. Petition for an Extension of Time (1 page, in duplicate).
4. Amendment (13 pages).
5. Copy of Terminal Disclaimer filed in U.S. Application Serial No.10/232,175 (2 pages).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chang et al. Date Mailed: 9 December 2004

Serial No.: 09/710,239 Filed: 10 November 2000

Title: RECOMBINANT GELATINS

Assignee: FibroGen, Inc.

Docket No.: FP0400 US

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5. Copy of Terminal Disclaimer filed in U.S. Application Serial No.10/232,175 (2 pages).

TO: Leanne Price

From : Chih-Min Kam
Patent Examiner
Tel: (571) 272-0948

Total Pages: 2

Fax No: (650) 866-7202

Messages: Proposed Examiner's Amendment for 09/710,239 (docket No. FP0400 US).

Hello, Ms. Price:

Here is my proposed Examiner's Amendment. The reason for this amendment is the recombinant non-hydroxylated gelatin disclosed in the reference by Werten et al. (Yeast 15, 1087-1096, August 1999; number 68 on your IDS list). Please call me, so we can discuss this issue.

5/23/05

COPY

Proposed Examiner's Amendments to the Claims:

Claims 12, 90 and 99 have been amended as follows:

12. (Currently amended) A recombinant gelatin composition consisting essentially of recombinant gelatin polypeptides of a uniform molecular weight, wherein the gelatin polypeptide is hydroxylated.

90. (Currently amended) A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists of recombinant gelatin polypeptides of a uniform molecular weight, wherein the gelatin polypeptide is hydroxylated.

99. (Currently amended) A recombinant gelatin consisting of recombinant gelatin polypeptides of a uniform molecular weight, wherein the gelatin polypeptide is hydroxylated.

UNITED STATES PATENT AND TRADEMARK OFFICE

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41385 7590 03/30/2005

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30 June 2005
Issue Fee &
Drawings due

EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/30/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

TITLE OF INVENTION: RECOMBINANT GELATINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$700	$0	$700	06/30/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

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I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

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P.O. Box 1450
Alexandria, Virginia 22313-1450

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41385 7590 03/30/2005

FIBROGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
225 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

TITLE OF INVENTION: RECOMBINANT GELATINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$700	$0	$700	06/30/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAM, CHIH MIN	1653	435-069100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

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(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

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1 _____

2 _____

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3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:

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☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office. U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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SEP 22 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

41385 7590 03/30/2005

FIBROGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
225 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/30/2005

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 12/04) Approved for use through 04/30/2007.

Notice of Allowability	Application No.	Applicant(s)	
	09/710,239	CHANG ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12/13/04*.

2. ☒ The allowed claim(s) is/are *2-6,8,12,21,30,43-45,47,48,50,54-57,59,61,62,64-68,70-73,75-83,89,90,92-94,98 and 99*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No./Mail Date *11 (3/22/02)*.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20041207;20050316* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

SEP 22 [redacted]

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Leanne Price on March 17, 2005.

Examiner's Amendments to the Claims:

Claims 12, 90 and 99 have been amended as follows:

12. (Currently amended) A recombinant gelatin composition consisting essentially of recombinant human gelatin polypeptides of a uniform molecular weight.

90. (Currently amended) A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin consists of recombinant human gelatin polypeptides of a uniform molecular weight.

99. (Currently amended) A recombinant gelatin consisting of recombinant human gelatin polypeptides of a uniform molecular weight.

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention. Werten *et al.* (Yeast 15, 1087-1096 (February 1999)) teach a recombinant non-hydroxylated gelatins based on mouse type I and rat type III collagen, however, the reference does not teach a recombinant human gelatin or a recombinant hydroxylated gelatin. A provisional obviousness type double patenting rejection made to co-pending application 10/232,175 (filed August 30, 2002), which is filed after the filing date of instant application (filed November 10, 2000), is withdrawn in view of no other rejections remained (see MPEP 804 IB). Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
March 17, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER

Interview Summary	Application No.	Applicant(s)	
	09/710,239	CHANG ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Chih-Min Kam*. (3)_____.

(2) *Leanne Price*. (4)_____.

Date of Interview: *17 March 2005*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *12,90 and 99*.

Identification of prior art discussed: *Werten et al. (Yeast 15, 1087-1096 (1999)*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *To amend claims 12, 90 and 99 as indicated in the Examiner's Amendment*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

[illegible] 2 2 [illegible]

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Interview Summary	Application No.	Applicant(s)	
	09/710,239	CHANG ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Chih-Min Kam*. (3)*Jim Nesbitt*.

(2) *Leanne Price*. (4)*Jon Weber*.

Date of Interview: *07 December 2004*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *4,12,89 and 98*.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Discussing the rejection under 35 U.S.C. 102(e) and 112, second paragraph; applicants will remove the term "homogeneous" and amend the claims with the limitations having more clearly definition in the amendment* .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

DEC 22 2004

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

PTO/SB/21 (01-03)
Approved for use through 04/30/2003. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

U.S. Serial No.	09/710,239
Filing Date	10 November 2000
Applicant(s)	Chang et al.
Art Unit	1653
Examiner Name	C. Kam
Docket No.	FP0400 US

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [x] Replacement sheets of corrected drawings (12 sheets) (Figures 1, 2A, 2B, 3, 4A, 4B, 5, 6A, 6B, 6C, 7A, 7B, 8, 9, 10A, 10B, 10C, 10D, 10E, 10F, 11A, 11B, 11C, 11D, 12A, 12B, 13, 14, 15A, 15B, and 16).
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] AppealCommunication to Group **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):
  Form PTOL-85 (1 page, in duplicate).
  Amendment Under 37 C.F.R. 1.312 (7 pages, in duplicate).

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	James E. Nesbitt, Ph.D. Reg. No. 54,575
Signature	
Date	19 May 2005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on this date: 19 May 2005.

Typed or printed	Carolyn C. Caires		
Signature	Carolyn C. Caires	Date	19 May 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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SEP 22 2005

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PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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41385 7590 03/30/2005

FIBROGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
225 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

Carolyn C. Caires	(Depositor's name)
Carolyn C. Caires	(Signature)
19 May 2005	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

TITLE OF INVENTION: RECOMBINANT GELATINS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$700	$0	$700	06/30/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
KAM, CHIH MIN	1653	435-069100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
   - ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
   - ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
   (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
   (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 James E. Nesbitt
2 Leanne C. Price
3 FibroGen, Inc.

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: FIBROGEN, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): South San Francisco, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:
- ☒ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):
- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☒ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number 50-0811 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date 19 May 2005 MAY 22 2006

Typed or printed name James E. Nesbitt, Ph.D. Registration No. 54,575

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 19 May 2005.

Carolyn C. Caires

Printed: Carolyn C. Caires

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Chang et al.	Assignee:	FibroGen, Inc.
Serial No.:	09/710,239	Filing Date:	10 November 2000
Examiner:	C. Kam	Group Art Unit:	1653
Title:	RECOMBINANT GELATINS		

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. 1.312

Sir:

Applicants request the following amendments to the specification, claims, and drawings be entered pursuant to 37 C.F.R. 1.312.

SEP 22 2005

IN THE SPECIFICATION

Please amend the specification as indicated below.

At page 8, replace the paragraph beginning at line 36 with the following paragraph:

Figures 4A and 4B set ~~Figure 4 sets~~ forth results demonstrating the production of hydroxylated recombinant gelatins.

At page 9, replace the paragraph beginning at line 6 with the following paragraph:

Figures 6A, 6B, and 6C set ~~Figure 6 sets~~ forth results showing the stability of recombinant gelatins expressed in the presence or absence of prolyl 4-hydroxylase.

At page 9, replace the paragraph beginning at line 9 with the following paragraph:

Figures 7A and 7B set ~~Figure 7 sets~~ forth results demonstrating enhanced recombinant gelatin expression by supplementation of expression media.

At page 31, replace the paragraph beginning at line 27 with the following paragraph:

The present invention provides recombinant gelatins of uniform molecular weight or specified ranges of molecular weights, removing variability and unpredictability, and allowing for fine-tuning of processes and predictable behavior. The present methods allow for ~~fro~~ the production of recombinant gelatins of any desired molecular weight or range of molecular weights. For example, in one embodiment, the recombinant gelatin has a molecular weight greater than 300 kDa. In another embodiment, the recombinant gelatin has a molecular weight range of from about 150 to 250 kDa, or of from about 250 to 350 kDa. Other molecular weight ranges are specifically contemplated, including, but not limited to, the following molecular weight ranges: about 0 to 50 kDa, about 50 to 100 kDa, about 100 to 150 kDa, about 150 to 200 kDa, about 200 to 250 kDa, about 250 to 300 kDa, and about 300 to 350 kDa.

At page 60, replace the paragraph beginning at line 10 with the following paragraph:

Endotoxin levels of commercial materials typically range from about 1.0 to 1.5 EU/mg of gelatin. (See, e.g., ~~Schaegger~~ Schagger, H. and G. von Jagow (1987) Anal. Biochem. 166:368-379; Friberger, P. et al. (1987) ~~in "Detection of Bacterial Endotoxins with the Limulus Amoebocyte Lysate Test,"~~ Prog. Clin. Biol. Res. 231:149-169.) In the methods of the present invention, the endotoxin levels can be reduced by two to three orders of magnitude. (See Example 8.) The

SEP 22 2003

present invention thus provides, in one embodiment, a recombinant gelatin derived from human sources that is virtually endotoxin-free.

At page 79, replace the paragraph beginning at line 12 with the following paragraph:

A 1048 bp Cel II-AgeI fragment was isolated from pDO7 which contained the 3' portion of the AOX1 promoter region, the mating factor alpha secretion signal, the recombinant gelatin of SEQ ID NO:19, the polylinker sequence from pPICZαA, and 56 base pairs of the AOX1 transcription terminator. This fragment was ligated into the Cel II-AgeI sites of pPIC9K (Invitrogen) to create pDO41. *Pichia pastoris* strain αβ8 (*his4*) was transformed with StuI-linearized plasmid pDO41 by electroporation, plated on minimal dextrose plates, and transformants were selected that complemented the *his4* auxotrophy. Approximately 20 his^+ transformants were grown and induced with methanol as described in Example 1. Strains that expressed SEQ ID NO:19 were identified by SDS-PAGE analysis of the conditioned media. (Figures 4A and 4B~~Figure 4~~.)

At page 79, replace the paragraph beginning at line 23 with the following paragraph:

Recombinant gelatin fragments from positive strains were purified from the media by acetone precipitation, and analyzed further by amino acid analysis, as described, e.g., in Hare, PE. (1977) Methods in Enzymology 47:3-18. Amino acid analysis of the gelatin product from one of the strains demonstrated the presence of hydroxyproline in the secreted recombinant gelatins. The ratio of hydroxyproline to proline was determined to be 0.29 in gelatin isolated from the strain shown in shown in Figures 4A and 4B ~~Figure 4~~, isolate #2, indicating co-expression of gelatin and prolyl 4-hydroxylase.~~.~~

At page 80, replace the paragraph beginning on line 36 with the following paragraph:

An 18 kDa recombinant gelatin (SEQ ID NO:20) was expressed according to the methods described above. The expressed fragments were analyzed by gel electrophoresis. Recombinant gelatin expressed in the presence of prolyl 4-hydroxylase had markedly greater stability than the gelatin expressed in the absence of prolyl 4-hydroxylase. (See Figures 6A, 6B, and 6C ~~Figure 6~~.)

At page 81, replace the paragraph beginning on line 17 with the following paragraph:

Transformants were selected by resistance to 500 μg/ml zeocin. Eight isolates from each transformation were grown and induced as described, and the stability of the expressed recombinant human gelatin was analyzed by SDS-PAGE. (See Figures 6A, 6B, and 6C ~~Figure 6~~.) In wild-type *Pichia pastoris* strain X-33, approximately equimolar amounts of intact recombinant gelatin and a proteolytic fragment (which migrated just below the recombinant gelatin on the gel, indicated by the arrow at the right of the figure) were observed. (Figure 6A, strain X-33.) In both strains that co-express prolyl 4-hydroxylase, the amount of the proteolytic fragment was significantly reduced, demonstrating that co-expression of prolyl 4-hydroxylase along with recombinant human gelatin enhanced gelatin stability by substantially reducing

proteolysis of the gelatin. (Figures 6B and 6C ~~Figure 6~~, strain P4H-2 and strain αβ8, respectively.)

At page 81, please replace the paragraph beginning on line 30 with the following paragraph:

Previous reports have indicated that casamino acid-supplemented media decreased the amount of proteolysis seen during expression of certain proteins in *Pichia pastoris*. (Clare, J.J. et al. (1991) Gene 105:202-215.) The breakdown of the present recombinant human gelatin expressed in *Pichia pastoris* was measured following enrichment of the expression media with various supplements. In this particular study, the *Pichia pastoris* strain αβ8 described in Example 5, which expressed recombinant human gelatin fragment SEQ ID NO:20 was employed. (Example 5 and Table 2.) Recombinant gelatin was induced in media supplemented with a range of concentrations (0-2%) of various supplemental components, including casamino acids, casitone, yeast extract, peptone, peptamin, tryptone, Gelatone, lactalbumin, and soytone. Several formulations, including lactalbumin hydrolysate, soytone, casitone, and peptamin (Difco Laboratories, Detroit, MI) increased recombinant gelatin expression levels. (Figures 7A and 7B ~~Figure 7~~, lactalbumin and soytone, respectively.)

IN THE CLAIMS

Please amend claim 93 as indicated below.

93. (Currently Amended) A pharmaceutical composition comprising a recombinant gelatin and a pharmaceutically acceptable excipient, wherein the recombinant gelatin has a percentage hydroxylation selected from the group consisting of greater than 0% to 20%, 20 to 80%, and 80 to 100%.

IN THE DRAWINGS

See attached replacement sheets of corrected drawings, containing Figures 1, 2A, 2B, 3, 4A, 4B, 5, 6A, 6B, 6C, 7A, 7B, 8, 9, 10A, 10B, 10C, 10D, 10E, 10F, 11A, 11B, 11C, 11D, 12A, 12B, 13, 14, 15A, 15B, and 16. The two panels of originally filed Figure 4 are now labeled Figure 4A and Figure 4B, respectively. A "10 kDa" marker appeared next to the right-hand panel of Figure 4 as originally filed, now Figure 4B and now appears next to corrected Figure 4A, as well. The extraneous text that appeared next to the left-hand panel of Figure 4 as originally filed has been deleted.

The three panels of originally filed Figure 6 are now labeled Figure 6A, Figure 6B, and Figure 6C, respectively. The molecular weight markers and other designations that appeared by the top panel of originally filed Figure 6, now Figure 6A, have been duplicated in each of the remaining panels, Figure 6B and Figure 6C, respectively, for clarity.

The two panels of originally filed Figure 7 are now labeled Figure 7A and Figure 7B, respectively.

The extraneous text that appeared at the bottom of the panels in Figures 9, 10A, 10B, 10C, 10D, 10E, 10F 11A, 11B, 11C, 11D, 12A, 12B, and 13 as originally filed has been deleted.

All amendments to the drawings were made to correct formalities as required by the Notice of Draftsperson's Patent Drawing Review (Form PTO-948) (Paper No. 11, Mail Date 3/22/02). No new matter is added by any of the amendments to the drawings, and entry of these amendments is thus respectfully requested.

REMARKS

Justification for the amendments is as follows. The amendments to the specification and to claim 93 correct mere typographical errors. Justification for the amendments to the drawings is as described above. No new matter is added by any of the above amendments.

As the amendments merely embody the correction of formal matters in the specification, claims, and drawings, Applicants respectfully request that all the amendments be entered on the recommendation of the primary examiner, and approved by the Commissioner, without withdrawing the application from issue.

Please call Applicant's representative directly at 650-866-7289 with any questions regarding this communication.

Respectfully submitted,

Date: 19 May 2005

By: James E. Nesbitt

James E. Nesbitt, Ph.D.
Reg. No. 54,575

FIBROGEN, INC.
225 Gateway Boulevard
South San Francisco CA 94080
Main: 650-866-7200
Direct: 650-866-7289
Facsimile: 650-866-7292

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chang et al. Date Mailed: 19 May 2005

Serial No.: 09/710,239 Filing Date: 10 November 2000

Title: RECOMBINANT GELATINS

Assignee: FibroGen, Inc.

Docket No.: FP0400 US

Please confirm receipt of the following items by return receipt of this postcard:

1. Transmittal (1 page).
2. Part B – Fee(s) Transmittal (PTOL-85) (1 page, in duplicate).
3. Amendment Under 37 C.F.R. 1.312 (7 pages, in duplicate).
4. Twelve (12) Replacement sheets of corrected drawings (Figures 1, 2A, 2B, 3, 4A, 4B, 5, 6A, 6B, 6C, 7A, 7B, 8, 9, 10A, 10B, 10C, 10D, 10E, 10F, 11A, 11B, 11C, 11D, 12A, 12B, 13, 14, 15A, 15B, and 16).

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JN

FP0400US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

41385 7590 11/01/2005

FIBROGEN, INC.
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/01/2005

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Please find below and/or attached an Office communication concerning this application or proceeding.

SEP 22 2006

PTO-90C (Rev. 10/03)

COPY

Response to Rule 312 Communication	Application No.	Applicant(s)	
	09/710,239	CHANG ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

1. ☒ The amendment filed on *23 May 2005* under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☒ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.
Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER

22 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT NO.	: 6,992,172
U.S. SERIAL NO.	: 09/710,239
INVENTOR(S)	: Chang, et al.
ISSUE DATE	: 31 January 2006
DOCKET NO.	: FP0400 US
TITLE	: RECOMBINANT GELATINS

Commissioner for Patents
PO Box 1450
Alexandria VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. 1.323

Sir:

Applicants request correction of the above-referenced issued U.S. Patent by Certificate of Correction pursuant to 37 C.F.R. 1.323. The text of the correction is submitted herewith on Certificate of Correction Form PTO/SB/44.

Enclosures:

1. Form PTO/SB/44 (1pg)

The Commissioner is hereby authorized to charge the total of the fee due in this communication to Deposit Account No. 50-0811. This form is enclosed in duplicate.

Please call Applicants' representative at 650.866.7289 with any questions regarding this communication or the above-referenced patent.

Respectfully submitted,

Date: 14 Sept 2006

By: _____

James E. Nesbitt, Ph.D.
Reg. No. 54,575

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jnesbitt@fibrogen.com

SEP 22 2006

Certificate of mailing or transmission under 37 CFR § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 14 September 2006.

Name: Michael Moores Signature: _____

PTO/SB/44 (04-05)
Approved for use through 04/30/2007. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,992,172

APPLICATION NO.: 09/710,239

ISSUE DATE : 31 January 2006

INVENTOR(S) : Chang, Robert C., et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 11, Line 61, please delete "simularity" and replace with --similarity--

Column 36, Line 29, please delete "non-consitutive" and replace with --non-constitutive--

Column 47, Line 3, please delete "manufature" and replace with --manufacture--

MAILING ADDRESS OF SENDER (Please do not use customer number below):

James E. Nesbitt, Ph.D.
FibroGen, Inc.
225 Gateway Boulevard
South San Francisco CA 94080

SEP 22 2008